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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,437	10/31/2001	Eric Schaeffer	PC10245AJAK	9719

7590 10/07/2004

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,437

Applicant(s)

SCHAEFFER, ERIC

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 23-33 and 36-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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Applicant's election with traverse of Group I, claims 1-22, 34 and 35 in the reply filed on 9/20/04 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search all the claims. This is not found persuasive because each of the Groups are independent and distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

This application contains sequences, all sequence requirements must be met. On page 21 line 14 of the present specification, "buccal administration" is queried.

The present specification on page 9 first full paragraph, discusses PTPbr7 as a negative regulator of NGF signaling and possible uses of inhibitors. It would appear the point of novelty of the present invention is the selection of this specific PTP, the PTPbr7 in the claimed assay.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22, 34, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sharma in view of each of Wipf, Huang, Daum and Harder.

Sharma (J of Biological Chemistry) entitled "A Neuronal Protein Tyrosine Phosphatase Induced by Nerve Growth Factor" teaches on page 49, that protein tyrosine phosphorylation has been demonstrated to play an important role in the regulation of neural growth and differentiation which is controlled by PTP's and PTK's. The role of PTP's and NGF is discussed. On page 52 column 1 last paragraph, PTPbr7 is not inhibited by substances which are known to inhibit other PTP's. On page 51 column 1 first full paragraph, a brief description of phosphatase activity assays is shown. On page 52 a number of inhibitors were tested.

The claims differ from Sharma in that they include limitations drawn to particulars of the method of assay. The following references are cited to show many particulars of the assay of inhibitors of PTP's in general.

Wipf (Biotechnology & Bioengineering) entitled "Synthesis and Biological Evaluation of a Targeted Library of Protein Phosphatase Inhibitors" teaches assays of inhibitors of PTP's.

Huang (J of Biomolecular Screening) entitled "3,6-Fluorescein Diphosphate: A Sensitive Fluorogenic and Chromogenic Substrate for Protein Tyrosine Phosphatase" teaches assays of inhibitors of PTP's.

Daum (Anal Biochemistry) entitled "A General Peptide Substrate for Protein Tyrosine Phosphatases" teaches assays of inhibitors of PTP's.

Harder (Biochem J) entitled "Characterization and Kinetic Analysis of the Intracellular Domain of Human Protein Tyrosine Phosphatase beta Using Synthetic Phosphopeptides" teaches assays of inhibitors of PTP's.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to assay inhibitors of any known PTP's such as PTPbr7 as taught by Sharma with any known method of assaying inhibitors of PTP's as taught by each of Wipf, Huang, Daum and Harder because Sharma teaches assaying inhibitors of a specific known PTP with the same standard methods known for assaying inhibitors of other PTP's. The secondary references teach various methods of assaying other PTP's. One would have a high expectation of success in employing any known method of assaying inhibitors of any PTP's for their known function applied to any known specific PTP. No novelty is seen in the selection of any known features of such assays with the expected result. Regarding the selection of the presently claimed PTP, PTPbr7, no result of the assay is claimed to distinguish the claimed selection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 34, 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The present claims are directed to identifying an agent that inhibits PTP. The specification has Examples 2 and 3 of an inhibition assay where the test agent is a known inhibitor, sodium orthovanadate. No test compounds are disclosed in the specification, no data of any compounds is presented. Only that PTPbr7 is inhibitable is seen. There are many confounding factors and variables that have not been addressed where the difficulty in obtaining useful data in such assays is known in this art.

The use of the trademark Tween-20 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1(a) line 2, "capable of" is improper, what actually occurs must be claimed. "Which is dephosphorylated" may be intended. In claim 1(b) "the ingredients" lacks antecedent basis. There are many instances of lack of antecedent basis in the claims, for example claim 1(d) "said incubation, 1(e) "the amount", claim 22 "the optical

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density", claim 22, "said stopped cocktails". Claims 19 and 20 contain trademarks which is improper. In claim 21 DTT and BME should be spelled out in the first occurrence in the claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Acton (6,258,582) teaches protein tyrosine kinase and phosphatase inhibitors.

Klingmuller (5,659,012) teaches phosphorylation and dephosphorylation with kinases.

Melcher (6,521,414) teaches protein tyrosine phosphatase agonists and antagonists.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200